# 510(k) SUMMARY
# BD Diagnostics BD GeneOhm™ MRSA ACP Assay

DEC 15 2009

Submitted By: BD Diagnostics (GeneOhm Sciences Canada Inc.)
2555, Boul. du Parc-Technologique
Québec (Québec)
Canada
G1P 4S5

Contact: Patricia Dionne, Ph.D.

Date Prepared: December 11, 2009

Name of Device:

| | |
|---|---|
| Trade Name: | BD GeneOhm™ MRSA ACP Assay |
| Common Name: | MRSA Detection Assay |
| Type of Test: | Nucleic Acid Amplification test, DNA, qualitative |
| Classification Name: | System, Test, Genotypic Detection, resistant and non-resistant markers, *Staphylococcus* colonies |
| Regulation Number: | 866.1640 |
| Product Code: | NQX |
| Classification advisory committee: | Microbiology |

Predicate Devices: BD GeneOhm™ MRSA Assay (K042357)
Cepheid Xpert MRSA Assay (K070462)

Device Description:

Intended Use:
The BD GeneOhm™ MRSA ACP Assay is a qualitative *in vitro* diagnostic test for the direct detection of methicillin-resistant *Staphylococcus aureus* (MRSA) DNA from nasal swabs in patients at risk for nasal colonization. The test utilizes polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD GeneOhm™ MRSA ACP Assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose MRSA infections nor to guide or monitor treatment for MRSA infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.

Test Description:
A nasal specimen is collected and transported to the laboratory using a recommended swab. The lysis of bacterial cells in nasal swab specimens is performed using the BD GeneOhm™ MRSA ACP Lysis kit. An aliquot of the lysate is added to prepared PCR reagents which contain MRSA-specific primers that will amplify in the presence of genetic target. The assay also includes an Internal Control (IC) to monitor for the presence of inhibitors in the PCR reaction and to confirm the integrity of assay reagents.

Controls and specimen lysates are added to disposable reaction tubes and placed in the SmartCycler® II instrument. The amplification, detection and results interpretation are automatically performed by the SmartCycler® II software. The BD GeneOhm™ MRSA ACP Assay procedure can be performed within 2 hours, depending on the number of specimens processed. To recover MRSA for epidemiological typing or for further antibiotic susceptibility testing, appropriate culture media can be inoculated during or up to 24 hours after specimen preparation.

The primers and probes in the BD GeneOhm™ MRSA ACP Assay detect a proprietary sequence inserted into the *S. aureus* chromosome indicating the presence of MRSA DNA. Amplification of IC and MRSA DNA are detected using specific hybridization probes that bind to a specific sequence of the amplified target. Differentiation of MRSA DNA and IC is done using molecular beacons which contain different fluorometric properties. The beacon-target hybrid fluoresces at a different wavelength for MRSA and IC and the emitted light from this reaction is measured by the SmartCycler® II instrument. MRSA or IC specific amplicons are detected simultaneously in two different fluorescence channels on the SmartCycler and can therefore be differentiated. The operation of the SmartCycler® II instrument is based on the proprietary microprocessor-controlled I-CORE® (Intelligent Cooling/Heating Optical Reaction) module.

Substantial Equivalence:

The BD GeneOhm™ MRSA ACP Assay is substantially equivalent the BD GeneOhm™ MRSA Assay (K042357) and the Cepheid Xpert MRSA Assay (K070462).

Performance Data:

Clinical performance characteristics of the BD GeneOhm™ MRSA ACP Assay were determined in a multi-site prospective investigational study. Three (3) investigational centers participated in the study. The Comparative Reference Method consisted of an initial analysis on a selective chromogenic media followed by subculture on Blood Agar (BA) of presumptive *S. aureus* colonies. Identification was confirmed with an agglutination test, while methicillin-resistance was confirmed by cefoxitin disk diffusion susceptibility testing. Results obtained for 1216 specimens are summarized in Tables 1 to 4.

Table 1: Results Obtained with the BD GeneOhm™ MRSA ACP Assay in Comparison with the Reference Method

| | | Comparative Reference Method + | Comparative Reference Method - | |
|---|---|---|---|---|
| BD GeneOhm™ MRSA ACP Assay | + | 172 | 56 | 228 |
| | - | 15 | 973 | 988 |
| | | 187 | 1029 | 1216 |

Table 2: Performance Obtained using the BD GeneOhm™ MRSA ACP Assay in Comparison with the Reference Method

| Clinical Sites | Prevalence | Sensitivity with 95% CI* | Specificity with 95% CI* |
|---|---|---|---|
| Site 1 | 11.6% (67/579) | 94.0% (85.4%, 98.3%) | 96.7% (94.7%, 98.1%) |
| Site 2 | 17.5% (56/320) | 88.9% (77.4%, 95.8%) | 89.8% (85.4%, 93.2%) |
| Site 3 | 20.1% (66/329) | 92.4% (83.2%, 97.5%) | 95.1% (91.7%, 97.3%) |
| Overall | 15.4% (189/1228) | 92.0% (87.1%, 95.4%) | 94.6% (93%, 95.9%) |

* CI: Confidence Intervals

Table 3: Unresolved Rates

| Clinical Sites | Initial unresolved rate with 95% CI* | | Unresolved rate after repeat with 95% CI* | |
|---|---|---|---|---|
| Site 1 | 1.0% (6/579) | (0.4% - 2.2%) | 0.0% (0/579) | (0.0% - 0.6%) |
| Site 2 | 0.3% (1/308) | (0.0% - 1.8%) | 0.0% (0/308) | (0.0% - 1.2%) |
| Site 3 | 1.5% (5/329) | (0.5% - 3.5%) | 0.0% (0/329) | (0.0% - 1.1%) |
| Overall | 1.0% (12/1216) | (0.5% - 1.7%) | 0.0% (0/1216) | (0.0% - 0.3%) |

* CI: Confidence Intervals

Table 4: Overall Invalid Run Rates

| Site | Invalid Run Rates with 95% CI* | |
|---|---|---|
| Site 1 | 0.0% (0/25) | (0.0% - 13.7%) |
| Site 2 | 4.5% (1/22) | (0.1% - 22.8%) |
| Site 3 | 9.5% (2/21) | (1.2% - 30.4%) |
| Overall | 4.4% (3/68) | (0.9% - 12.4%) |

* CI: Confidence Intervals

Analytical Sensitivity:

Limit of Detection (LoD) Determination Using Genomic DNA:

The analytical sensitivity (limits of detection or LoDs) of the BD GeneOhm™ MRSA ACP Assay testing genomic DNA were determined using decreasing amount of quantified (copies/PCR reaction) genomic DNA from cultures of 6 MRSA strains that represent 6 MREJ genotypes (i, ii, iii, iv, v, and vii) and 4 SCC*mec* types (I, II, III, IV). Each MRSA strain was tested in replicates of 48 per concentration by 2 different operators using 3 different lots of lyophilized BD GeneOhm™ MRSA ACP Assay Master Mixes. Analytical sensitivity (LoD), defined as the lowest concentration at which ≥ 95% of all replicates tested positive, ranged from 2.5 to 5 copies/PCR reaction, with an average value of 5 DNA copies/PCR reaction.

| MRSA Strain | MREJ Genotype | SCCmec Type | LoD Concentration |
|---|---|---|---|
| 1 | type i | I | 5 copies/PCR reaction |
| 2 | type ii | II | 5 copies/PCR reaction |
| 3 | type iii | III | 5 copies/PCR reaction |
| 4 | type iv | III | 5 copies/PCR reaction |
| 5 | type v | IV | 2.5 copies/PCR reaction |
| 6 | type vii | II | 5 copies/PCR reaction |

Limit of Detection (LoD) Determination Using Viable Bacteria with Clinical Nasal Matrix:
The analytical sensitivity (limits of detection or LoDs) of the BD GeneOhm™ MRSA ACP Assay testing viable MRSA strains with clinical nasal matrix were determined using simulated positive swabs that were prepared by soaking swabs in a wide range of MRSA bacterial suspensions prepared and quantified from cultures of 6 MRSA strains that represent 6 MREJ genotypes (i, ii, iii, iv, v, and vii) and 4 SCC*mec* types (I, II, III, IV), and then discharged/eluted in pooled negative clinical nasal matrix. Each MRSA strain was tested in replicates of 24 per concentration by 2 different operators using 3 different lots of lyophilized BD GeneOhm™ MRSA ACP Assay Master Mixes. Analytical sensitivity (LoD), defined as the lowest concentration at which ≥ 95% of all replicates tested positive, ranged from 130 to 576 CFU/swab, with an average value of 300 CFU/swab.

| MRSA Strain | MREJ Genotype | SCC*mec* Type | LoD Concentration |
|---|---|---|---|
| 1 | type i | I | 207 CFU/swab |
| 2 | type ii | II | 576 CFU/swab |
| 3 | type iii | III | 256 CFU/swab |
| 4 | type iv | III | 245 CFU/swab |
| 5 | type v | IV | 130 CFU/swab |
| 6 | type vii | II | 386 CFU/swab |

Analytical Inclusivity:
Analytical ubiquity of the BD GeneOhm™ MRSA ACP Assay was evaluated in the analytical inclusivity study. A variety of *Staphylococcus aureus* strains were included in the study taking into account geographic origin, MREJ genotype, SCC*mec* type, pulse field gel electrophoresis (PFGE) type, temporal diversity and susceptibility pattern. One-hundred-forty (140) strains from 31 countries were tested in this analytical inclusivity study, including 52 from public collections and 88 from well-characterized clinical isolates, including Vancomycin-resistant *Staphylococcus aureus* (VRSA) and Vancomycin-intermediate *Staphylococcus aureus* (VISA) strains.

When tested at the relevant clinical load (roughly 100 genome copies/µL), 99% of all the strains were detected. The BD GeneOhm™MRSA ACP Assay detected all of the MREJ wild types i, ii, iii, iv, v and vii tested, as well as MREJ mutant types ii mut16, ii mut25 and iii mut25. The BD GeneOhm™ MRSA ACP Assay detected MRSA SCC*mec* types I, II, III, IV, V and VI, as well as MRSA PFGE types USA 100 to 800, 1000 and 1100. All *Staphylococcus aureus* strains displaying additional resistance to vancomycin (VRSA and VISA) were also detected. When the same strains were tested in triplicate at concentrations < 3X LoD, 83% were detected in all three replicates and 99% were detected in at least one out of three replicates.

Evaluation of a Well Characterized Challenge Strain Panel:
An additional analytical study was carried out to evaluate the analytical performance of the BD GeneOhm™ MRSA ACP Assay by testing a well characterized challenge strain panel containing MRSA strains with high and low oxacillin minimum inhibitory concentrations (MICs), including PFGE types USA 100, 300, and 400 (with emphasis on

USA 300), BORSA (borderline oxacillin-resistant *S. aureus* strains are *mec*A negative, but exhibit oxacillin resistance by a mechanism not completely understood), methiciilin-sensitive *S. aureus* (MSSA), and methicillin-resistant *Staphylococcus epidermidis* (MRSE) strains. The challenge strain panel used in this study was composed of 15 MRSA, 4 BORSA, 1 MRSE and 5 MSSA strains. All MRSA strains tested belong to MREJ type ii, with the exception of one MRSA strain, which belonged to MREJ type iii. These strains have previously been shown to display a broad range of oxacillin and cefoxitin MICs. All these strains were tested with FDA-cleared broth dilution susceptibility tests for determination of the MIC values.

All the MRSA strains tested (including PFGE types USA 100, 300 and 400) exhibited positive results when tested at 2-3X LoD concentration. All BORSA, MSSA and MRSE strains tested exhibited negative results when tested at high concentrations.

Analytical Specificity:

Forty-one (41) out of 42 strains of various non-staphylococcal species tested at a concentration corresponding to ~ $3 \times 10^5$ copies/PCR reaction (~ $7 \times 10^7$ CFU/swab) produced negative results with the BD GeneOhm™ MRSA ACP Assay. One (1) strain was reported as positive by the BD GeneOhm™ MRSA ACP Assay. Investigation demonstrated that the positive result obtained was due to MRSA contamination.

Nineteen (19) Methicillin susceptible Coagulase Negative *Staphylococci* (MSCNS) strains, 15 Methicillin resistant Coagulase Negative *Staphylococci* (MRCNS) strains and 2 Coagulase Negative *Staphylococci* (CNS) strains tested with the BD GeneOhm™ MRSA ACP assay produced negative results. The specificity with Coagulase Negative *Staphylococci* was 100%.

106 out of 111 MSSA strains tested at extremely high concentrations, ~ $3 \times 10^5$ copies/PCR reaction (~ $7 \times 10^7$ CFU/swab), produced negative results with the BD GeneOhm™ MRSA ACP assay; the remaining 5 MSSA strains produced negative results at ~ $3 \times 10^4$ copies/PCR reaction (~ $7 \times 10^6$ CFU/swab). Therefore, the specificity of the BD GeneOhm™ MRSA ACP Assay with MSSA was 100% (111/111) at ~ $3 \times 10^4$ copies/PCR reaction (~ $7 \times 10^6$ CFU/swab), and 95.5% (106/111) at ~ $3 \times 10^5$ copies/PCR reaction (~ $7 \times 10^7$ CFU/swab).

Interfering Substances:

Eighteen (18) substances used in bacterial culture, transport media, as well as biological and chemical substances occasionally used in the nares or found in nasal swab specimens were evaluated for potential interference with the BD GeneOhm™ MRSA ACP Assay. MRSA positive specimens were tested at 3x the Limit of Detection (LOD) and at typical clinical concentration (Ct values in the FAM channel between 30.0 and 35.0) with the highest amount of each compound likely to be found at the sampling site or on the nasal swab specimens. Results demonstrated no reportable interference with any substance except for blood when present in excess. Rhinaris® and Secaris® at high concentrations showed slight inhibition in the BD GeneOhm™ MRSA ACP Assay, however, expected assay results were still obtained.

Endogenous and Commercial Exogenous Substances Tested with the BD GeneOhm™ MRSA ACP Assay

| Substance | Result | Substance | Result |
|---|---|---|---|
| Dristan® | NI | Mannitol Salt Agar plate | NI |
| Drixoral® | NI | CHROMagar | NI |
| Flonase® | NI | Liquid Amies | NI |
| Nasonex® | NI | Liquid Stuart | NI |
| Otrivin® | NI | Gel Amies | NI |
| Petroleum jelly | NI | Blood | I |
| Rhinaris® | NI* | Nasal Secretion | NI |
| Secaris® | NI* | Cromolyn eye drops® | NI |
| Tryptic Soy Broth | NI | Saline | NI |

NI: No reportable interference with the BD GeneOhm™ MRSA ACP Assay.
I: Detectable interference with the BD GeneOhm™ MRSA ACP Assay only if substance is present in excess.
* Rhinaris® and Secaris® at high concentrations showed slight inhibition in the BD GeneOhm™ MRSA ACP Assay, however, expected assay results were still obtained.

Reproducibility:

The reproducibility panel consisted of 4 specimen categories near the LoD. Each tube contained simulated nasal flora (*Staphylococcus epidermidis* (ATCC 14990)). Two MRSA strains were tested in each of the 4 categories, as follows:

- Moderate Positive (MP): 2 - 5X LoD
- Low Positive (LP): 1 - 2X LoD
- High Negative 1:10 (HN1:10): 10-fold dilution of 1X LoD
- High Negative 1:100 (HN1:100): 100-fold dilution of 1X LoD

A fifth category consisted of negative (Neg) specimens (simulated nasal flora and no MRSA).

Specimens in each category were tested in triplicate, on 5 distinct days, wherein each day 2 panels were tested by 2 technologists, at 3 clinical sites using 1 lot of reagents (Site-to-Site). One (1) of these clinical sites participated in an extended study where 2 additional lots of reagents were tested (Lot-to-Lot). Results are shown for each specimen category with the data from both MRSA strains pooled.

For Site-to-Site Reproducibility, the overall percent agreement was 100% for MP and Neg categories, 95.0% for LP, 88.3% and 47.2% negative agreement for HN1:100 and HN1:10 categories, respectively (Table 5).

For Lot-to-Lot Reproducibility, the overall percent agreement was 100% for MP and Neg categories, 98.3% for LP, 91.7% and 41.7% negative agreement for HN1:100 and HN1:10 categories, respectively (Table 6).

Cycle threshold (Ct), an internal criteria used to determine a final assay result, was selected as an additional means of assessing assay reproducibility. Overall mean Ct values with variance components (SD and %CV) are shown in Tables 5 and 6.

Table 5: Site-To-Site Reproducibility Study Results using One Lot

| Category | SITE | | | | | | Overall Percent Agreement | | Ct Values[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Site 1 | | Site 2 | | Site 3 | | | | | | |
| | Percent Agreement | | Percent Agreement | | Percent Agreement | | | | Overall Mean | SD | %CV |
| Neg | 30/30 | 100% | 30/30 | 100% | 30/30 | 100% | 90/90 | 100% | 34.9 | 0.3 | 0.9 |
| HN1:100[2] | 49/60 | 81.7% | 58/60 | 96.7% | 52/60 | 86.7% | 159/180 | 88.3% | 40.8 | 1.6 | 3.8 |
| HN1:10[2] | 26/60 | 43.3% | 27/60 | 45.0% | 32/60 | 53.3% | 85/180 | 47.2% | 39.8 | 1.5 | 3.8 |
| LP | 59/60 | 98.3% | 60/60 | 100% | 52/60[3] | 86.7% | 171/180 | 95.0% | 38.5 | 1.1 | 2.8 |
| MP | 60/60 | 100% | 60/60 | 100% | 60/60 | 100% | 180/180 | 100% | 36.8 | 1.0 | 2.6 |

[1] For the Neg category, CT values reported are for the internal control. For other categories, CT values reported are for the MRSA target.
[2] For the High Negative categories, the expected assay result was deemed to be negative. Therefore, percent agreement was calculated for negative results.
[3] Eight (8) LP specimens initially reported as negative were positive upon retesting from frozen lysates.

Table 6: Lot-To-Lot Reproducibility Study Results using Three Lots

| Category | LOT | | | | | | Overall Percent Agreement | | Ct Values[1] | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Lot 1 | | Lot 2 | | Lot 3 | | | | | | |
| | Percent Agreement | | Percent Agreement | | Percent Agreement | | | | Overall Mean | SD | %CV |
| Neg | 30/30 | 100% | 30/30 | 100% | 30/30 | 100% | 90/90 | 100% | 34.8 | 0.4 | 1.2 |
| HN1:100[2] | 58/60 | 96.7% | 54/60 | 90.0% | 53/60 | 88.3% | 165/180 | 91.7% | 39.9 | 1.1 | 2.7 |
| HN1:10[2] | 27/60 | 45.0% | 28/60 | 46.7% | 20/60 | 33.3% | 75/180 | 41.7% | 39.6 | 1.0 | 2.5 |
| LP | 60/60 | 100% | 58/60 | 96.7% | 59/60 | 98.3% | 177/180 | 98.3% | 38.2 | 0.9 | 2.4 |
| MP | 60/60 | 100% | 60/60 | 100% | 60/60 | 100% | 180/180 | 100% | 36.5 | 0.9 | 2.5 |

[1] For the Neg category, CT values reported are for the internal control. For other categories, CT values reported are for the MRSA target.
[2] For the High Negative categories, the expected assay result was deemed to be negative. Therefore, percent agreement was calculated for negative results.

Precision:

Within-laboratory precision was evaluated for the BD GeneOhm™ MRSA ACP Assay at 1 site. The study was performed using the same specimen categories and calculations as above. Testing was performed in duplicate, over 12 days, with 2 runs per day, by 2 technologists. All samples and controls produced reportable results except for 1 HN1:100 sample and 2 HN1:10 samples which produced unresolved results. Repeat testing with the frozen lysates produced reportable results. Precision study results for Neg, LP and MP samples demonstrated 100% agreement. Precision study results for HN1:100 and HN1:10 demonstrated agreement of 95.8% and 41.7%, respectively.

Carry-Over Contamination:

To evaluate the risk of carry-over while processing specimens with high MRSA bacterial load in the BD GeneOhm™ MRSA ACP Assay, an analytical study was carried out to evaluate the entire process from sample preparation (including utilization of septum and screw caps on lysis tubes) to PCR result. Two (2) MRSA strains (MREJ type ii and vii) were used as the high positive MRSA panel members ($1.4 \times 10^4$ copies/PCR reaction and $5.1 \times 10^4$ copies/PCR reaction respectively). Negative members were prepared with Sample Buffer. Three (3) replicates of each high positive panel member (a total of 6 high positives) and 6 replicates of the negative panel member were tested by alternating negative and positive samples. Each run contained positive and negative controls prepared according to the package insert. All panel members and controls were processed following the BD GeneOhm™ MRSA ACP Lysis Kit package insert and the BD GeneOhm™ MRSA ACP package insert. The same experiment was performed by 4 operators with each of the two types of lysis tube cap (septum and screw caps). The experiment was performed a second time 72 hours later using the original run controls from the first experiment to assess for possible contamination during storage.

No false positive result due to carry-over contamination was observed over a total of 16 runs (8 with septum caps tubes and 8 with screw caps tubes by 4 operators). Storage of the PC and NC tubes at 4°C for 72 hours and the subsequent use in retesting did not lead to invalid runs or carry-over contamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

**Food and Drug Administration**
**10903 New Hampshire Avenue**
**Document Mail Center-WO66-G609**
**Silver Spring, MD 20993-0002**

DEC 15 2009

BD Diagnostics (GeneOhm Sciences, Inc.)
c/o Mr. Raymond Boule
Senior Director, Regulatory Affairs
6146 Nancy Ridge Drive
San Diego, CA 92121

Re: k093346
Trade Name: BD GeneOhm MRSA ACP Assay
Regulation Number: 21 CFR §866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Codes: NQX
Dated: October 22, 2009
Received: October 26, 2009

Dear Mr. Boule:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5460. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Linda A. Cole for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**510(k) Number (if known):** K093346

**Device Name:** BD GeneOhm™ MRSA ACP Assay

**Indication for Use:**

The BD GeneOhm™ MRSA ACP Assay is a qualitative *in vitro* diagnostic test for the direct detection of methicillin-resistant *Staphylococcus aureus* (MRSA) DNA from nasal swabs in patients at risk for nasal colonization. The test utilizes polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD GeneOhm™ MRSA ACP Assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose MRSA infections nor to guide or monitor treatment for MRSA infections. Concomitant cultures are necessary only to recover organisms for epidemiological typing or for further susceptibility testing.

| Prescription Use: | X | AND/OR | Over-The-Counter Use: | — |
|---|---|---|---|---|
| (Per 21 CFR 801 Subpart D) | | | (Per 21 CFR 801 Subpart C) | |

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

---

**Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD)**

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety (OIVD)

510(k): K093346